



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: SAM F. LIPRIE)
SERIAL NUMBER: 09/681,303) Group Art Unit:
FILED: March 15, 2001) 3641
FOR: FLEXIBLE SOURCE WIRE FOR) Before the Examiner:
RADIATION TREATMENT OF) Jack Keith
DISEASES)

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APPEAL BRIEF

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(1) REAL PARTY IN INTEREST

The real party in interest is Interventional Therapies, L.L.C.

(2) RELATED APPEALS AND INTERFERENCES

There are no interferences that may have a bearing on the present appeal. An appeal is currently pending, and an appeal brief has been filed in related United States Patent Application Serial No. 09/455,582, filed December 6, 1999 and in related United States Patent Application Serial No. 09/455,579, filed December 6, 1999.

(3) STATUS OF CLAIMS

Claims 1-31 are currently pending in the present application. A clean copy of claims 1-31, as amended, are attached hereto as Appendix 1. A Final Office Action was mailed on April 8, 2003, finally rejecting claims 1-31. Applicant appeals from the final rejection of claims 1-31.

(4) STATUS OF AMENDMENTS

Claims 1-31 were originally presented with the filing of the application on March 15, 2001. Claim 13 was amended in the response dated February 6, 2003, paper No. 14.

(5) SUMMARY

The appealed claims are related to a unique source wire used to deliver a radioactive source to a remote treatment site. This source wire advantageously features a generally cylindrical, elongated housing tube, through which a flexible backbone wire extends to a point

adjacent a positioned, encapsulated radiation source or adjacent capsule into which a radiation source is provided. The housing tube is constructed of a material exhibiting little or no memory retention when bent. Thus, the housing tube possesses shape memory characteristics that permit the source wire to adequately and, more to the point, repeatedly navigate torturous regions of the body. (See *e.g.*, the Applicant's specification, paragraphs [0007] and [0009]).

Reference is made to the Applicant's Figure 3, which shows exemplary features of construction of the presently presented source wire, which further provide resiliency and/or integrity to the wire such that repeated use may be made through torturous regions. The material of the outer, housing tube 12 already being discussed, a flexible backbone wire 14 is presented through a length of the housing tube 12 up to a thin walled capsule 20, into which a radioactive source 16 may be loaded. Such thin-walled capsule both protects the radioactive source from damage and prevents contamination of the remainder of the wire, and contributes, in combination with the nickel and titanium alloy housing tube and flexible backbone wire to the resiliency and/or integrity of the wire, which permits such repeated use without risk of either partial or total failure of the wire. (See *e.g.*, the Applicant's specification at paragraphs [0017], [0019] and [0021]).

Thus, the aggregate result of the above features advantageously provides a resilient, flexible wire useful in modern medicine for radiation treatment of diseases in remote areas of the body.

For the convenience of the Examiner and the Board, the three independent claims are reproduced below:

Independent claim 1 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube; and

a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.

Independent claim 13 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube; and

a radiation source or sources provided within said housing tube.

Independent claim 24 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube;

a capsule inserted into the proximal of said flexible elongated housing tube;

a radiation source or sources inserted into said capsule; and

a plug which seals said proximal end of said housing tube.

(6) ISSUES

The following issues are drawn from the last non-final Office Action on the merits (Paper No. 12) as modified by the last final Office Action on the merits (Paper No. 14):

WPM (A) Claims 1-31 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

(B) Claims 1-6, 9-15, 17-25 and 27-31 were rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,282,781 to Liprie (hereinafter "Liprie '781").

(C) Claims 7, 8, 16 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie '781 in view of either U.S. Patent No. 5,163,896 to Suthanthiran (hereinafter "Suthanthiran") or U.S. Patent No. 5,395,300 to Liprie (hereinafter "Liprie '300").

(D) Claims 1-6, 9-15, 7-25 and 27-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie '781 in view of U.S. Patent No. 5,454,794 to Nariciso et al. (hereinafter "Nariciso") and U.S. Patent No. 5,230,348 to Ishibe et al. (hereinafter "Ishibe").

(7) GROUPING OF CLAIMS

The claims herein stand or fall together.

(8) ARGUMENT

(A) The rejection of claims 1-31 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claims 1-31 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Specifically, the Examiner has cited to the claim language within claims 1-31 as being unclear whether the housing tube is positively recited as being part of the flexible source wire.

The Applicant notes that each of claims 1, 13 and 24 explicitly recites "a flexible, hollow, elongated housing tube..." in the body of the claim. Because such is explicitly recited, it is a part of the flexible source wire.

The Examiner also noted concern with language describing "future acts" (specifically, the terminology "when bent"), indicating that such is not a positive structural limitation.

As a first point, whether the source wire is bent or straight is not a temporal limitation. The wire could be presently bent or presently straight (i.e., when claimed). There is no future action implied. Rather, such is a limitation that serves to define a characteristic of the materials of certain source wire components. In that respect, *In re Collier* does not apply.

As a second point, the decision in *In re Collier* is conditioned by the subsequent case *In The Matter Of The Application Of J. William Venezia*, 530 F.2d 956; 189 U.S.P.Q. (BNA) 149 (CCPA 1976). That case specifically discussed the *In re Collier* decision, noting that "conditional" language itself is not suspect, where such claims "precisely define present structural attributes of interrelated component parts...such that later assembly...may be effected." *Id* at 960.

For the above reasons, the rejection is improper and should be withdrawn.

(B) *The rejection of claims 1-6, 9-15, 17-25 and 27-31 under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,282,781 to Liprie (hereinafter "Liprie '781").*

Review of the independent claims reveals that the presently pending claims patentably distinguish over Liprie '781. As will be pointed out below, Liprie '781 lacks particular required limitations described by the independent claims. Because all of the required claim limitations are

not described by the cited reference, an anticipation rejection is improper.

Each of independent claims 1 and 13 and 24 may be readily distinguished over Liprie '781 in that Liprie '781 fails to teach or suggest either of a "housing tube constructed from a material having little or no memory retention when bent." With respect to claim 24, Liprie '781 fails to teach or suggest either of a " housing tube constructed from a material having little or no memory retention when bent " or "a capsule inserted into said proximal end of the flexible elongated housing tube."

Rather, Liprie '781 teaches a housing tube constructed of either of stainless steel, tantalum or titanium (not a shape memory material). *See* Col. 6, lines 24-29.

This is wholly distinct from the above-stated requirements of claims 1, 13 or 24. Because these limitations are not taught or suggested (that is, since all of the limitations have not been identified in the cited art), the Examiner's rejections should be withdrawn.

Further with regard to the above, the Examiner stated in the Official Action, that Liprie '781 teaches encapsulation of radioactive sources, generally. The Applicant notes that while the reference does teach providing a radioactive source within a capsule, it does not teach placing that capsule material within a housing tube. Rather, the specification (at Column 4, lines 10-24) teach a wire like that of U.S. Patent No. 4,861,520 to Van't Hooft (hereinafter Van't Hooft), which was the sole U.S. reference of record in the '781 patent. That reference describes a capsule holding a radioactive source, which is either simply welded to a sheared end of a drive cable, or which is welded to a plug which is simply welded to a sheared end of a drive cable (all components stainless steel). Thus, neither Liprie '781, nor Van't Hooft, which displayed the type of construction referred to by Liprie '781, teaches the source wire construction provided for by

the present claims.

Accordingly, the rejection should be reversed.

(C) *The rejection of claims 7, 8, 16 and 26 under 35 U.S.C. 103(a) as being unpatentable over Liprie '781 in view of either U.S. Patent No. 5,163,896 to Suthanthiran (hereinafter "Suthanthiran") or U.S. Patent No. 5,395,300 to Liprie (hereinafter "Liprie '300").*

The Examiner uses Suthanthiran to show that encapsulation of radioactive sources is generally known. However, the Examiner should note that the radioactive seed of Suthanthiran is for direct placement within the body, not for inclusion within a flexible, elongated housing tube, as is required by claims 1 and 15.

Additionally, Suthanthiran does not describe a capsule, provided within a flexible, elongated housing tube, such as is required by claim 23. For this reason alone, the Examiner's rejection should be withdrawn with reference to claim 23.

As discussed above, Liprie '781 calls (1) for a radioactive source to be directly inserted within a housing tube between a backbone wire and a plug and (2) for the tube to be drawn down to secure each element in place. Liprie '781 teaches that the drawing down process removes all air space. This removal of air space prevents migration of radioactive flakes.

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). "The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01. "If the proposed modification or combination of the prior art would change the principle of

operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The proper motivation to combine Suthanthiran and Liprie '781 is not present. Suthanthiran does not suggest the desirability of including the seed within any other devices, and Liprie '781 does not suggest the desirability of including within the wire what would ordinarily be designed for direct intracorporeal use. The references do not suggest the desirability of such combination, and the Examiner cannot draw such motivation from the Applicant's roadmap. As stated in W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983),

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. ... One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

Because the requisite motivation to combine is lacking, the Examiner's rejections should be withdrawn.

With reference to the rejection with regard to Liprie '781 in combination with Narciso and Liprie '300, Liprie '300 is presented by the Examiner to show that rounding of backbone wires or capsules is known in the art. However, the independent claims 1, 13 and 24 do not include any such limitations.

Because the independent claims are patentable for the reasons described above, the Applicants need not address the teachings of the reference. Accordingly, the Examiner's rejection should be withdrawn.

(D) *The rejection of claims 1-6, 9-15, 7-25 and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Liprie '781 in view of U.S. Patent No. 5,454,794 to Nariciso et al. (hereinafter "Nariciso") and U.S. Patent No. 5,230,348 to Ishibe et al. (hereinafter "Ishibe").*

In order to make out a prima facie case of obviousness, a proposed combination of prior art references must teach or suggest all of the limitations of the rejected claims. *In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g.*, *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). "The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The Examiner also uses Narciso as evidence that (specifically) a nickel/titanium alloy (more generally, a material exhibiting little or no memory retention when bent), in general, is equivalent to stainless steel and tantalum (which are disclosed as suitable materials by Liprie '781). However, such a broad generalization is inappropriate. The Examiner improperly generalizes about the equivalence of different metals.

Rather, focus should be on whether the metals are equivalent for the particular constructions taught by the independent claims. With reference to the Nariciso patent, whether NITINOL, stainless steel or tantalum are equally suitable or not (in that for the application, the metals permit the construction to deflect and then return to their original position) as a deflecting wire within a steerable catheter is not determinative as to whether a nickel/titanium alloy (or indeed, a material that exhibits little or no memory retention when bent) is equally suitable (equivalent to) stainless steel or tantalum in the form of a housing tube for a source wire.

It is well known in the industry that stainless steel source wires tend to fail not only through repeated traversal of the torturous regions of the body, but may also tend to kink or distort during single applications in particularly tortuous regions. By contrast, the shape memory characteristics of the nickel and titanium alloy housing tube, specifically, and materials exhibiting little or no memory retention when bent, more generally, of the presently presented claims lends a resiliency to the wire, permitting the wire to repeatedly and reliably traverse the torturous regions of the body without risk of such distortion and kinking.

The Ishibe reference does not cure the deficiencies of Liprie '781 and Nariciso.

Because the requisite motivation to combine is lacking, the Examiner's rejections should be withdrawn.

(9) CONCLUSION

The rejections of the claims are in error and should be reversed.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account No. 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,

SAM F. LIPRIE

CANTOR COLBURN, L.L.P.

Applicant's Attorneys

By: 

H. M. Bedingfield

Registration No. 44,530

Date: October 27, 2003

Address: 55 Griffin Road South, Bloomfield, Connecticut 06002

Telephone: (860) 286-2929

APPENDIX I

[c1]

1. A flexible source wire for radiation treatment of diseases within a body comprising:
a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material $\left[\text{exhibiting little or no memory retention when bent;} \right]$
a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube; and
a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.

[c2]

2. The flexible source wire in accordance with claim 1 further including a plug which is sealed to said proximal end of said housing tube.

[c3]

3. The flexible source wire of claim 1, wherein said radioactive source is encapsulated within a neutron permeable material.

[c4]

4. The flexible source wire of claim 1, wherein said radioactive source is included within a thin walled-capsule.

[c5]

5. The flexible source wire in accordance with claim 1, wherein said backbone wire is completely disposed in said housing tube.

[c6]

6.The flexible source wire in accordance with claim 1 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.

[c7]

7.The flexible source wire in accordance with claim 4 wherein at least one end of said capsule is rounded.

[c8]

8.The flexible source wire in accordance with claim 3 wherein at least one end of said encapsulated radioactive source or sources is rounded.

[c9]

9.The flexible source wire in accordance with claim 1 wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.

[c10]

10. The flexible source wire in accordance with claim 1, wherein said backbone wire includes a distal end, and wherein said distal end is disposed within said tube.

[c11]

11.The flexible source wire in accordance with claim 1 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.

[c12]

12.The flexible source wire in accordance with claim 13 wherein said non-oxidizing agent is gold.

[c13]

13. A flexible source wire for radiation treatment of diseases within a body comprising:
a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;
a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube; and
a radiation source or sources provided within said housing tube.

[c14]

14. The flexible source wire in accordance with claim 13 further including a plug, which is sealed to said proximal end of said housing tube.

[c15]

15. The flexible source wire in accordance with claim 13 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.

[c16]

16. The flexible source wire in accordance with claim 13 wherein at least one end of said capsule is rounded.

[c17]

17. The flexible source wire in accordance with claim 13, wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.

[c18]

18. The flexible source wire in accordance with claim 13 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.

[c19]

19. The flexible source wire in accordance with claim 18 wherein said non-oxidizing agent is gold.

[c20]

20. The flexible source wire of claim 13, wherein the radioactive source is encapsulated within a neutron permeable material.

[c21]

21. The flexible source wire of claim 13, wherein the radioactive source is included within a thin-walled capsule.

[c22]

22. The flexible source wire in accordance with claim 13, wherein said backbone wire is completely inserted in said housing tube.

[c23]

23. The flexible source wire of claim 13, wherein the backbone wire includes a distal end, and wherein the backbone wire is completely inserted such that the distal end is disposed within the tube.

[c24]

24. A flexible source wire for radiation treatment of diseases within a body comprising:
a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube;

a capsule inserted into said proximal end of said flexible elongated housing tube;

a radiation source or sources inserted into said capsule; and

a plug which seals said proximal end of said housing tube.

[c25]

25. The flexible source wire in accordance with claim 24 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.

[c26]

26. The flexible source wire in accordance with claim 24 wherein at least one end of said capsule is rounded.

[c27]

27. The flexible source wire in accordance with claim 24 wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.

[c28]

28. The flexible source wire in accordance with claim 24 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.

[c29]

29. The flexible source wire in accordance with claim 28 wherein said non-oxidizing agent is gold.

[c30]

30. The flexible source wire in accordance with claim 24, wherein said backbone wire is completely disposed in said housing tube.

[c31]

31. The flexible source wire of claim 24, wherein the backbone wire includes a distal end, and wherein the backbone wire is disposed completely within the tube such that the distal end is disposed within the tube.